

REMARKS

Reconsideration of the above-referenced patent application is respectfully requested in view of the foregoing amendments and remarks set forth herein.

Claims 24 and 28 have been amended to insert the terminology from original claims 21 and 22, and claim 25 has been amended to clarify by the addition of the words "caused by". It is therefore submitted that no new matter has been added to this application.

In the Office Action of August 7, 2006, the Examiner took the following actions to which Applicant herein makes response: (1) noted use of a trademark and indicated that it should be capitalized and that other instances should be corrected as well; (2) objected to claims 24-26, 28, 30-33 and 37-39, stating that these claims are dependent on non-elected claims; that claims 31 and 32 are substantially duplications and the claims 38 and 39 are substantially duplicates; (3) rejected claims 24-26, 28, 30-33 and 37-39 under 35 USC 112, first paragraph as being drawn too broadly with respect to the antigen; (4) rejected claims 31-32 and 38-39 under 35 USC 112, first paragraph regarding deposit of the particularly antibodies; (5) rejected claims 24-26, 28, 30-33 and 37-39 under 35 USC 112, first paragraph regarding the word "associated" and states that the specification does not describe the epitopes against which the claimed antibodies are raised ; (6) rejected claims 24-26, 28, 30-33 and 37-39 under 35 USC 112, second paragraph as omitting essential steps and not being clear on what is assayed; (7) rejected claims 24-26, 28, 30-33 and 37-39 under 35 USC 112, second paragraph as being indefinite with respect to "wherein said fungal infection is a Candida vaginitis or mucocutane candidiasis", "wherein said diagnosis is performed on mucosal secretions or urine", "said patient"; (8) rejected claims 24-26, 30 and 33 under 35 USC 102(b) as being anticipated by Brawner et al.; (9) rejected claims 24, 26, 28, 30 and 37 as being anticipated by Wakshull et al.; and (10) rejected claims 24-26, 30, and 33 under 35 USC 102(b) as being anticipated by Bargatze et al. These rejections are traversed in application to the claims as amended, and consideration is requested of the patentability of claims 24-25 and 28 now pending in the application.

(1) Use of trademark

Applicant has amended page 7 of the specification as required by the Examiner. Applicant's review of the specification has not located any other trademarks. Applicant therefore submits that this objection has been overcome.

(2) Objection to claims 24-26, 28, 30-33 and 37-39, stating that these claims are dependent on non-elected claims; that claims 31 and 32 are substantially duplications and the claims 38 and 39 are substantially duplicates

Claims 24, 25 and 28 have been amended to include the terminology of the non-elected claims from which they depended, and claims 31-32 and 38-39 have been withdrawn. It is therefore submitted that this objection is moot.

(3) Rejection of claims 24-26, 28, 30-33 and 37-39 under 35 USC 112, first paragraph as being drawn too broadly with respect to the antigen

Applicant respectfully submits that the amended claims herein correspond to the disclosed method with respect to species disclosed of antigen and antibody, and particularly corresponds to the examples given by Applicant in the specification. Thus, Applicant has amended claim 24 to recite: A method for the diagnosis of a fungal infection in a patient comprising assaying mucosal secretions or urine of the patient with at least one antibody reactive with a $\beta(1-3)$ glucan – and/or a $\beta(1-3)(1-6)$ – glucan epitope in free form, in cell wall fragments or on an intact cell surface and available in cell wall fragments of *C. albicans* and/or *C. neoformans*, or on the cell surface of *C. albicans*, *C. parapsilosis*, *C. krusei*, *C. glabrata* and/or *C. neoformans*. Claim 25 depends from claim 24, and claim 28 has been similarly amended to claim 24.

Applicant therefore submits that claims 24, 25 and 28 pending herein are patentable under 35 USC 112, first paragraph.

(4) Rejection of claims 31-32 and 38-39 under 35 USC 112, first paragraph regarding deposit of the particularly antibodies

Claims 31-32 and 38-39 have been withdrawn, and this rejection is therefore moot.

(5) Rejection of claims 24-26, 28, 30-33 and 37-39 under 35 USC 112, first paragraph regarding the word “associated” and states that the specification does not describe the epitopes against which the claimed antibodies are raised

As stated above, Applicant respectfully submits that claims 24, 25 (dependent from 24) and claim 28, the amended claims herein, correspond to the disclosed method with respect to species disclosed of antigen and antibody, and particularly corresponds to the examples given by Applicant in the specification. Further, the term “associated” no longer appears in the claims.

Applicant therefore respectfully submits that claims 24, 25 and 28 pending herein are patentable under 35 USC 112, first paragraph.

(6) Rejection of claims 24-26, 28, 30-33 and 37-39 under 35 USC 112, second paragraph as omitting essential steps and not being clear on what is assayed

Applicant has amended claim 24 to recite: A method for the diagnosis of a fungal infection in a patient comprising assaying mucosal secretions or urine of the patient with at least one antibody reactive with a $\beta(1-3)$ glucan – and/or a $\beta(1-3)(1-6)$ – glucan epitope in free form, in cell wall fragments or on an intact cell surface and available in cell wall fragments of *C. albicans* and/or *C. neoformans*, or on the cell surface of *C. albicans*, *C. parapsilosis*, *C. krusei*, *C. glabrata* and/or *C. neoformans*. Applicant respectfully submits that it is clear that the essential step is to assay, and that the remaining information that is important to how to assay, or look for a reaction, between the specified antibody and the substance assayed (mucosal secretions or urine of the patient) are included inherently in the claim as amended. If the Examiner determines that the step of assaying should be modified and more specifically outlined in the claim, for example, by using terms such as selecting a patient, obtaining a sample, running an antibody test, analyzing the results of the antibody test, etc., Applicant can do so, but Applicant respectfully submits that these components of the methodology of the invention of assay are clear from the claim as amended.

Therefore, Applicant respectfully submits that claims 24, 25 and 28 pending herein are patentable under 35 USC 112, first paragraph.

(7) Rejection of claims 24-26, 28, 30-33 and 37-39 under 35 USC 112, second paragraph as being indefinite with respect to “wherein said fungal infection is a *Candida* vaginitis or mucocutane candidiasis” (claims 25 and 33), “wherein said diagnosis is performed on mucosal secretions or urine” (claim 26), “said patient” (claims 28, 37-39)

Applicant respectfully submits that the first of these terms is now clear due to the amendment of claim 25 to recite “caused by *Candida* vaginitis or mucocutane candidiasis”, and thus the claim no longer appears to be *Candida* vaginitis or mucocutane candidiasis but rather to be caused by these. Claim 33 has been withdrawn.

With respect to the second of these terms, claim 26 has been canceled.

With respect to the third of these terms, claim 28 has been amended appropriately to provide sufficient antecedent, and claims 27-29 have been withdrawn.

Therefore, Applicant respectfully submits that claims 24, 25 and 28 pending herein are patentable under 35 USC 112, second paragraph.

(8) Rejection of claims 24-26, 30 and 33 under 35 USC 102(b) as being anticipated by Brawner et al.

Brawner et al. discloses oral *Candida* isolates from immunocompromised patients, and in particular, discloses antibodies to mannose and glucose as pointed out by the Examiner. While Brawner’s antigens are cell-surface, nothing in Brawner teaches or suggests “assaying mucosal secretions or urine of the patient with at least one antibody reactive with a $\beta(1-3)$ glucan – and/or a $\beta(1-3)(1-6)$ – glucan epitope in free form, in cell wall fragments or on an intact cell surface and available in cell wall fragments of *C. albicans* and/or *C. neoformans*, or on the cell surface of *C. albicans*, *C. parapsilosis*, *C. krusei*, *C. glabrata* and/or *C. neoformans*” (emphasis added).

Applicant therefore submits that claims 24, 25 (dependent on claim 24) and 28 are patentable under Section 102(b) over Brawner et al.

(9) Rejection of claims 24, 26, 28, 30 and 37 as being anticipated by Wakshull et al.

Wakshull et al discloses methods of isolating $\beta(1-3)$ -glucan or $\beta(1-3)$ -glucan-containing organisms in a sample, utilizing binding agents such as lactosylceramide, galactosyl ceramide, globotriaosylceramide and asialoganglioside-GM1 (e.g., claim 4 of Wakshull et al.). These particular substances are compounds that are not antibodies. While Wakshull et al. mentioned that antibodies can be used (page 6, line 10), Wakshull et al. neither teach or suggest “assaying mucosal secretions or urine of the patient” or “diagnosis of a fungal infection in a patient comprising assaying mucosal secretions or urine of the patient” as found in claim 24 as amended. Claim 26 has been similarly amended.

Applicant therefore submits that claims 24, 25 (dependent on claim 24) and 28 are patentable under Section 102(b) over Wakshull et al.

(10) Rejection of claims 24-26, 30, and 33 under 35 USC 102(b) as being anticipated by Bargatze et al.

Bargatze et al. discloses antibodies against hydrophobic proteins that are protective against candidiasis, and claims a monoclonal antibody that specifically binds to a cell wall protein of *Candida* as well as a method of treating candidiasis by administering the antibody. Nothin in Bargatze et al. teaches or suggests “**assaying** mucosal secretions or urine of the patient” or “**diagnosis** of a fungal infection in a patient comprising assaying mucosal secretions or urine of the patient” (emphasis added) as found in claim 24 as amended. Claim 26 has been similarly amended.

Applicant therefore submits that claims 24, 25 (dependent on claim 24) and 28 are patentable under Section 102(b) over Bargatze et al.

Conclusion

For all the foregoing reasons, claims 24, 25 and 26 are submitted to be fully patentably distinguished over the cited references and in allowable condition. Favorable consideration is therefore requested.

No new claims have been added to the previously pending claims. It is therefore believed that no fee is required for the presentation of this amendment except for the separately submitted Petition for Extension of Time. Any additional amounts that may be

due for presentation of this amendment should be charged to Deposit Account No. 02-0825 of Applicant's attorney.

If any questions or issues remain, the resolution of which the Examiner feels would be advanced by a personal or telephonic conference with Applicant's attorney, the Examiner is invited to contact such attorney at the telephone number noted below.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Lynn E. Barber", with a long horizontal flourish extending to the right.

Lynn E. Barber
Attorney for Applicants
Registration No. 31,734
P.O. Box 16528
Fort Worth, TX 76162
(817) 361-7131

Enclosures:

Petition for Extension of Time and fee